## 10/582385

### IAP20 Rec'd PCT/PTQ 09 JUN 2006

Docket No.: 4705-0121PUS1 (PATENT)

#### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:

Marco Antônio SANTINI et al.

Application No.: NEW

Confirmation No.: N/A

Filed: June 9, 2006

Art Unit: N/A

For:

PROCESS FOR THE PREPARATION OF

ANHYDROUS AND HYDRATED ACTIVE PHARMACEUTICAL INGREDIENTS (APIS); STABLE PHARMACEUTICAL COMPOSITIONS PREPARED FROM THE

SAME AND USES OF SAID

**COMPOSITIONS** 

Examiner: Not Yet Assigned

#### **INFORMATION DISCLOSURE STATEMENT (IDS)**

MS PCT Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

Pursuant to 37 CFR 1.56, 1.97 and 1.98, the attention of the Patent and Trademark Office is hereby directed to the references listed on the attached PTO/SB/08. It is respectfully requested that the information be expressly considered during the prosecution of this application, and that the references be made of record therein and appear among the "References Cited" on any patent to issue therefrom.

This Information Disclosure Statement accompanies the new patent application submitted herewith.

Applicant has not submitted copies of each cited U.S. patent and U.S. patent application as required by 37 CFR 1.98(a)(2)(i), amended October 2004, as the U.S. Patent and Trademark

Office has waived this requirement for all U.S. patent applications. Applicant submits herewith copies of foreign and non-patents in accordance with 37 CFR 1.98(a)(2).

Those documents which are marked with a double asterisk (\*\*) next to the Cite No. in the attached form PTO/SB/08 (facsimile) are not supplied because they were previously cited by or submitted to the Office in a prior application number PCT/BR2004/000242, filed December 10, 2004 and relied upon in this application for an earlier filing date under 35 U.S.C. 120.

A concise explanation of relevance of the items listed on form PTO/SB/08 is in the form of an English language copy of a Search Report from a foreign patent office, issued in a counterpart application, which refers to the relevant portions of the references.

In accordance with 37 CFR 1.97(g), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made or that no other material information as defined in 37 CFR 1.56(a) exists. In accordance with 37 CFR 1.97(h), the filing of this Information Disclosure statement shall not be construed to be an admission that any patent, publication or other information referred to therein is "prior art" for this invention unless specifically designated as such.

It is submitted that the Information Disclosure Statement is in compliance with 37 CFR 1.98 and the Examiner is respectfully requested to consider the listed references.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to our Deposit Account No. 02-2448 for

2 DRN/dns

## 10/582385

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Application No.: NEW

any additional fees required under 37 C.F.R. § 1.16 or under § 1.17; particularly, extension of time fees.

Dated: June 9, 2006

Respectfully submitted,

By Mark J. Whell, Ph.D.

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## IAP20 Rec'd PCT/PTO 09 JUN 2006

PTO/SB/08a/b (07-05)

Approved for use through 07/31/2006. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

| Substitute for form 1449A/B/PTO               |                 |         |              | Complete if Known      |                       |  |
|---|-----------------|---------|--------------|------------------------|-----------------------|--|
|   |                 |         |              | Application Number     | NEW 0 / 502705        |  |
| INFORMATION DISCLOSURE STATEMENT BY APPLICANT |                 |         |              | Filing Date            | Jun 0.6582385         |  |
|   |                 |         |              | First Named Inventor   | Marco Antônio SANTINI |  |
|   |                 |         |              | Art Unit               | N/A                   |  |
|   | (Use as many sh | eets as | s necessary) | Examiner Name          | Not Yet Assigned      |  |
| Sheet   | 1               | of      | 1            | Attorney Docket Number | 4705-0121PUS1         |  |

| U.S. PATENT DOCUMENTS |              |   |                  |  |   |
|-----------------------|--------------|---|------------------|--|---|
| Examiner<br>Initials* | Cite<br>No.1 | Document Number                           | Publication Date | Name of Patentee or<br>Applicant of Cited Document | Pages, Columns, Lines, Where<br>Relevant Passages or Relevant<br>Figures Appear |
|                       |              | Number-Kind Code <sup>2</sup> ( if known) |                  |  |   |
|                       | AA*          | US-5,475,120-A                            | 12-12-1995       | RAO  |   |
|                       | AB*          | US-6,002,025-A                            | 12-14-1999       | PAGE   |   |
|                       | AC*          | US-2004/0116720-A1                        | 06-17-2004       | SHARMA et al.                                      |   |

| FOREIGN PATENT DOCUMENTS |              |   |                                   |                             |   |                  |
|--------------------------|--------------|---|-----------------------------------|-----------------------------|---|------------------|
| Examiner<br>Initials*    | Cite<br>No.1 | Foreign Patent Document   | Publication<br>Date<br>MM-DD-YYYY | Name of Patentee or         | Pages, Columns, Lines,<br>Where Relevant Passages<br>or Relevant Figures Appear |                  |
|                          |              | Country Code <sup>3</sup> -Number <sup>4</sup> -Kind Code <sup>5</sup> (if known) |                                   | Applicant of Cited Document |   | l T <sub>6</sub> |
|                          | BA**         | WO-1996/022984-A1   | 08-01-1996                        |                             |   |                  |

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. \* CITE NO.: Those application(s) which are marked with an single asterisk (\*) next to the Cite No. are not supplied (under 37 CFR 1.98(a)(2)(iii)) because that application was filed after June 30, 2003 or is available in the IFW. \*\* CITE NO.: Those document(s) which are marked with an double asterisk (\*\*) next to the Cite No. are not supplied because they were previously cited by or submitted to the Office in a prior application relied upon in this application for an earlier filing date under 35 U.S.C. 120. ¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at <a href="https://www.uspto.gov">www.uspto.gov</a> or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁴ Applicant is to place a check mark here if English language Translation is attached.

| NON PATENT LITERATURE DOCUMENTS |  |  |  |  |  |
|---------------------------------|--|--|--|--|--|
|                                 | T²   |  |  |  |  |
|                                 | title of the item (book,<br>er(s), publisher, city |  |  |  |  |

<sup>\*</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

| Examiner  | Date       |  |
|-----------|------------|--|
| Signature | Considered |  |

<sup>&</sup>lt;sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup>Applicant is to place a check mark here if English language Translation is attached.